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Part III

Office of Science and Technology Policy

Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee; Notice

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Establishment of the Biotechnology Science Coordinating Committee.

SUMMARY: This Federal Register Notice Announces the Establishment of the Biotechnology Science Coordinating Committee and publishes the revised matrix of U.S. laws related to biotechnology.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Rabin, Assistant Director, Office of Science and Technology Policy, Executive Office of the President, New Executive Office Building, Washington, D.C. 20506.

Jerry D. Jennings,

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November 8, 1985.

Table of Contents

I. Introduction

On December 31, 1984, the Federal agencies that insure the safety of biotechnology research and products published a proposal for a coordinated framework for the regulation of biotechnology. The framework contained: A concise index of U.S. laws related to biotechnology; the proposed policies of the major Federal agencies that will be reviewing the research and products of biotechnology; a proposed scientific advisory mechanism for coordinating the responses to scientific questions raised by applications received by the various involved agencies; and, a proposal for interagency coordination of regulatory activities related to biotechnology. The Federal Register Notice requested that comments be submitted.

Comments addressed both the agency-specific regulatory proposals and the science advisory mechanism on particular issues and offered suggestions. The comments have been very useful in helping to refine particular aspects of the proposals. The interagency science review mechanism and the matrix of U.S. laws related to biotechnology have been revised and completed. They are the subjects of this notice and are presented in section II. and III. below. The remainder of this introduction briefly describes the status of the respective agency regulatory policies, the agency-based science advisory mechanisms, and interagency coordination of regulatory activities.

A revised statement of the regulatory policies of the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture, and the Occupational Safety and Health Administration will be published early next year; the target date is January 31, 1986. The regulatory policies described in the overall framework, because of their technical complexity, require greater time for review and revision.

The Food and Drug Administration received 34 comments, one-half from private industry or associations representing private industry regulated by FDA. The comments generally supported the current FDA regulatory policies for products of biotechnology.

The Environmental Protection Agency received comments from 68 organizations and individuals. Commentors addressed: EPA's authority under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); EPA's proposed definition of "new" microorganisms and the scope of the premanufacture notice requirements under TSCA; the need for interagency coordination; the need for a scientific review mechanism and other issues.

The Department of Agriculture received 50 comments plus an additional 15 references included in comments submitted to OSTP. These comments addressed both research and regulatory issues concerning efficacy, safety, and environmental considerations for plants, animals, and microbes in the agroecosystem. The two largest categories of respondents were business and academia, followed closely by associations representing these interests.

The Occupational Safety and Health Administration separately published a notice in the **Federal Register**, April 12, 1985. Comments to that Notice supported OSHA's proposed approach to consider specific regulations for biotechnology in the event that genetically engineered organisms present a significant hazard that cannot be dealt with by existing standards.

The National Science Foundation, the Department of Agriculture, and the Environmental Protection Agency are developing agency-based science advisory mechanisms to provide expert advice when needed. These agency-based committees will address agency-specific science issues related to agriculture and the environment, and thus serve to augment and complement the on-going role of The National Institutes of Health Recombinant DNA Advisory Committtee relating primarily to biomedical research.

The National Science Foundation will utilize the Advisory Committee for Biological, Behavioral and Social Sciences on issues relating to the needs and impacts of NSF sponsored research. This committee is advisory to the Director of the Foundation, and to the Assistant Director for Biological, Behavioral and Social Sciences. Members include approximately 10 persons selected from the scientific community for their eminence in their respective fields. They represent a broad range of disciplines within the biological, behavioral and social science. The chairperson is appointed from within the committee membership by the Assistant Director for Biological, Behavioral and Social Sciences. Subcommittees composed of selected outside experts in a specific field, will continue to serve as a means for obtaining special expert advice on selected topics. Meetings of the committee are open to the public except when a written determination is made that a meeting or portion should be closed pursuant to exemptions under the Government in Sunshine Act, Section 552b, Title 5, United States Code.

The Department of Agriculture will establish a Committee on Biotechnology in Agriculture (CBA) to assist in assuring that research and regulatory decisions are based upon the best available science. The CBA will be under the co-jurisdiction of the Assistant Secretary for Science and Education and the Assistant Secretary for Marketing and Inspection Services.

The agency-based committee for the Environmental Protection Agency is being established and will be announded in the **Federal Register** no later than January 31, 1986. The Food and Drug Administration does not intend to establish an advisory committee dedicated specifically to biotechnology. FDA has in place a number of mechanisms to insure available scientific expertise including FDA advisory committees organized according to areas of clinical applications (e.g., metabolic and endocrine drugs; vaccines; blood and blood products and the like).

In addition to the coordination of scientific review, the **Federal Register** Notice of December 31, 1984, recognized the need for coordination of regulatory activities of the federal government. It was noted that an interagency

mechanism is needed to foster timely and coordinated decision making via interagency communication on matters of regulation; discuss matters of jurisdiction among agencies; serve as a mechanism by which agencies can raise public concerns; and consider generic approaches for translating risk assessment information into policy decisions.

Also recognized was the need for this continuing coordination mechanism to address the broader issues within the regulatory process itself. "Although at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology, there are always potential problems and deficiencies in the regulatory apparatus in a fast moving field. We believe this interagency coordinating committee should monitor the changing scene of biotechnology and serve as a means of identifying potential gaps in regulation in a timely fashion, making appropriate recommendations for either administrative or legislative action."

The Notice concluded that for the time being the Cabinet Council Working Group on Biotechnology established under the former Cabinet Council on Natural Resources and the Environment could serve these needs and, when its activities were completed, some other interagency coordinating committee would be established to continue this effort.

Since the date of the former Notice, the Cabinet Council Working Group on Biotechnology efforts became the Domestic Policy Council Working Group on Biotechnology. That new Working Group is now serving these needs. As with the former Working Group, the Chair is the Director, Office of Science and Technology Policy. He is now assisted by the Assistant Director for Biological, Behavioral and Social Sciences of the National Science Foundation, and staff support is provided by the Office of Science and Technology Policy. This Notice reflects the effort of the Domestic Policy Council Working Group.

II. The Biotechnology Science Coordinating Committee

The Federal Register Notice of December 31, 1984 proposed the establishment of a two-tier mechanism for addressing emerging scientific questions. A lower tier, agency-based science advisory committee(s) would provide guidance to an agency. A second tier, parent board in the form of an advisory committee would provide interagency review and coordination. At the first tier the research-sponsoring agencies (NIH and NSF) and the regulatory agencies (Agriculture, EPA and FDA) would utilize their respective science advisory committees for outside expert guidance in answering scientific questions raised by applications seeking approval for scientific research or for product testing or marketing. For NIH, the agency-based committee was identified as the Recombinant DNA Advisory Committee (RAC). This agency approach, however, was not thought to be sufficient for inter-agency coordination in an area of such rapid and scientific progress. In particular, new scientific issues arising frequently could be of concern to several agencies. Thus, there should be a formal mechanism for communication and coordination among the involved agencies for emerging scientific issues and their review as conducted by the agency-based scientific advisory committees.

Accordingly, a Biotechnology Science Board (BSB) was proposed that would be chartered by the Department of Health and Human Services, reporting to the Assistant Secretary for Health. The BSB membership would include members from each agency-based science advisory committee. The BSB would:

Receive from each agency a summary of each application relating to recombinant RNA, recombinant DNA, or cell fusion which is submitted to one of the agency-based scientific advisory committees; and may make a request to the submitting agency that another committee or the parent board itself undertake a review of a specific proposal or classes of proposals.

Review committee reports, redacted and supplemented as stated above.

Evaluate review procedures set by the agency-based scientific advisory committees.

Conduct analyses of broad scientific issues involving rRNA, rDNA, or cell fusion and other processes as needed.

Develop generic scientific guidelines that can be applied to similar, recurring applications.

Provide a forum for public concerns.

The comments to the proposal raised various concerns. Of the seventy-nine submitted to OSTP, almost half addressed some aspect of the BSB. The structure of the Board received many comments. Twenty-five comments reflected concern that the two-tiered structure with two levels of science advisory committees was too cumbersome, and that the possible double review procedures would impose unreasonable delay and become a disincentive to development of new biotechnology products. Eight were concerned with the ability of the BSB to protect confidential business information. Sixteen expressed the view that the BSB should function as a "super RAC" (a multiagency version of the successful NIH Recombinant DNA Advisory Committee) and they expressed a desire to have it organizationally located within the office of the Assistant Secretary for Health, HHS. Seven were concerned that a BSB would detract from the RAC, impairing its stature and function.

Other opinions were expressed that the BSB: should set guidelines on policy for scientific review, but should not be a review board; should provide advisory, not binding reviews; should review an application only at the request of an agency; and, should include ethical and social considerations in a review.

In light of these concerns, modifications to the BSB were considered. There remained a general consensus that coordination of science questions arising from applications received by the research and regulatory agencies was very desirable. However, there was no need for a second level advisory committee review. Accordingly, it was recognized that interagency information sharing and coordination could be effectively carried out by a structure offering interagency coordination rather than by an advisory committee.

An interagency coordinating committee composed of senior representatives from the involved agencies including NIH, NSF, Agriculture, EPA, and FDA could serve these needs. This interagency committee could provide federal agency officials from different agencies a forum for discussing scientific questions raised in regulatory and research applications and, thus, make available a wider understanding of emerging scientific questions and promote consistency in agency approaches. Because only federal officials would be involved, scientific data contained in commercial and research applications made to agencies could be shared since confidential business information or other proprietary data could be appropriately protected. A coordinating committee could address issues of public concern brought to it by the agencies and could hold meetings open to the public.

With a decision to establish an interagency coordinating committee, the question of the proper location for the committee was considered. HHS had been the proposed organizational location for the BSB; however, several factors suggested that another location might be preferable. HHS contains within it two groups that would be members of the coordinating committee,

namely the NIH and the FDA. Maintaining the committee within HHS could give the impression of a bias toward an HHS point of view. Also locating the committee within HHS might raise the appearance of rivalry between it and the NIH RAC, even though the functions of the RAC and the coordinating committee would be very different. Similarly, placing the coordinating committee within another research or regulatory agency could also raise the appearance of an agency bias or the appearance of a conflict between the coordinating committee and the agency's agency-based science advisory committee. In fact, in light of all factors considered, a location apart from any single regulatory or research agency, seemed to be the preferable organizational location.

The Federal Coordinating Council for Science, Engineering and Technology (FCCSET) appeared to be a suitable organizational location and structure under which to place functions of the coordinating committee. The FCCSET is a statutory interagency coordinating mechanism housed within the Office of Science and Technology Policy, Executive Office of the President, with a mission to coordinate federal science activities among federal agencies. Committees are established under FCCSET to address particular science concerns. Accordingly, a FCCSET committee is being established to coordinate science issues related to research and commercial applications of biotechnology, the Biotechnology Science Coordinating Committee (BSCC).

The charter of the BSCC clearly establishes its interagency coordination role. The purposes of the BSCC are to:

Serve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus;

Promote consistency in the development of Federal agencies' review procedures and assessments;

Facilitate continuing cooperation among Federal agencies on emerging scientific issues; and

Identify gaps in scientific knowledge.

The charter of the BSCC provides for the sharing of information related to scientific questions raised and authorizes the BSCC to receive information regarding the scientific aspects of biotechnology applications submitted to federal research and regulatory agencies for approval. The BSCC will conduct analyses of broad scientific issues that extend beyond those of any one agency and develop generic scientific recommendations that can be applied to similar, recurring applications. And the BSCC is authorized to convene workshops and symposia, and coordinate special studies related to scientific issues in biotechnology.

The members of the BSCC are senior policy officials at each of the involved agencies. Initial members of the BSCC are:

Department of Agriculture
- Assistant Secretary for Marketing and Inspections Services
- Assistant Secretary for Science and Education

Department of Health and Human Services
- Commissioner, Food and Drug Administration
- Director, National Institutes of Health

Environmental Protection Agency
- Assistant Administrator for Pesticides and Toxic Substances
- Assistant Administrator for Research and Development

National Science Foundation
- Assistant Director for Biological, Behavioral & Social Sciences

The BSCC is chaired by the Assistant Director for Biological, Behavioral and Social Sciences of the National Science Foundation and the Director of the National Institutes of Health on a rotating basis.

The BSCC will meet on a periodic basis depending on its workload. The BSCC will discuss emerging scientific questions raised by biotechnology, brought to the agencies in research or regulatory applications. The BSCC will not conduct a second level review of applications and, therefore, will not delay agency decisionmaking. On the other hand, it is hoped that the general information discussed at BSCC meetings and other information shared will provide an information base to agency officials that will in fact assist them in evaluating new applications.

The BSCC will seek input from the public on issues of generic interagency concern. For such issues, BSCC meetings may be open to the public, and BSCC prepared written guidance may be available for public comment.

III. Revised Regulatory Matrix

The matrix outlines laws, regulations and guidelines that may be applicable to biotechnology products at some point in research, development, marketing, shipment, use or disposal. To aid in understanding current requirements, the matrix has been divided into seven parts which have been cross-referenced when necesssary:

I. Licensing and other premarketing requirements;
II. Post marketing requirements;
III. Export controls;
IV. Research and information gathering;
V. Patents;
VI. Air and water emissions; and
VII. Requirements for Federal agencies.

BILLING CODE 6160-01-M

BIOTECHNOLOGY AUTHORITIES

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
I. LICENSING AND OTHER PREMARKETING REQUIREMENTS					
Food, Drug and Cosmetic (FD&C) Act (21 USC 301-392) Regulations: 21 CFR Parts 1, 71, 171, 314, 514, 571, 807	Premarketing approval required for: drugs -- Sec. 505 medical devices -- Sec. 515 food additives -- Sec. 409 color additives -- Sec. 706 animal drugs -- Sec. 512	All human and animal drugs and human devices, food additives, animal feed additives, and color additives	HHS-FDA	Certain EPA statutes specifically exclude FD&C Act products. EPA sets tolerance levels for pesticide residues in the food chain. FDA provides human tolerance levels for animal drugs in food chain meat and poultry to the USDA-FSIS. Animal and human biologics are regulated under the Virus-Serum-Toxin Act (VST Act), a USDA statute, and the Public Health Service Act, respectively. FDA decisions are subject to National Environmental Policy Act (NEPA).	From the beginning of clinical research to premarketing approval takes for: human drugs: 5-10 years animal drugs: 3-5 years devices: 2-5 years direct food additives: 5-7 years indirect food additives: 3-5 years color additives: 5-9 years Important: FDA regulates biotechnology on a product-by-product basis. FDA will not be restructuring the process to regulate the products of biotechnology or the manufacturers of those products.
Public Health Service (PHS) Act Section 351(a) (42 USC 262) Regulations: 21 CFR 600-680	Licensing for marketing required for human biologics	Human biologics	HHS-FDA	USDA-APHIS licenses animal biologics produced by interstate manufacturers. FDA decisions are subject to NEPA.	The research use of investigational new drugs is regulated under the FD&C Act. From the beginning of clinical research to license takes approximately 2-8 years depending on the type of biologic, but 6-8 is more common.
"Points to consider in the characterization of cell lines used to produce biologicals"	FDA technical guidance for new product appproval	Human drugs and biologics	HHS-FDA		
"Points to consider in the manufacture of Monoclonal Antibody Products for Human Use"	FDA technical guidance for new product approval	Human drugs and biologics	HHS-FDA		FDA reviews the adequacy of testing of all products on a case-by-case basis.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
"Points to consider in the production and testing of new drugs and biologicals produced by rDNA technology"	FDA technical guidance for new product approval	Human drugs and biologics	HHS-FDA		New Investigational New Drug (IND) and biological licenses and/or new drug approvals are required currently with rDNA technology even if the active substance is identical in molecular structure to a previously approved product.
PHS Act Section 353 (42 USC 263a) Regulations: 42 CFR 74	License required for clinical laboratories engaged in interstate commerce	Laboratory services	HHS-CDC HHS-Health Care Financing Admin.		To meet licensure requirements, laboratories must meet proficiency testing, quality control, and personnel standards.
Virus-Serum-Toxin Act (21 USC 151-158) Regulations: 9 CFR 101-117 and 122-123	License required for any virus, serum, toxin, or analogous product intended for use in treatment of domestic animals which are shipped interstate or imported. Regulations contain standards of efficacy, purity, safety and potency. They also contain labeling provisions.	9 CFR 101.2(w) defines "biological products" to mean "all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals."	USDA-APHIS	USDA decisions are subject to NEPA. The definition of drugs in the FD&C Act includes biological products. The FD&C Act (21 USC 391) and its regulations exempt biological products regulated under the VST Act.	USDA's licensing policy for conventional or rDNA derived veterinary biologics is on a product-by-product basis, and requires that all license applicants for rDNA products comply with the NIH "Guidelines for Research Involving Recombinant DNA Molecules."
USDA's Licencing Policy for Biologicals Produced by rDNA	USDA technical guideline reviewing production and test considerations for evaluating rDNA product license applications.	Veterinary biologics and diagnostics	USDA-APHIS		Each veterinary biologic product is reviewed as a single entity. USDA evaluates each license application for conventional or rDNA biologics to ensure purity, potency, safety, and efficacy.
Veterinary Services Memorandum Number 800.68	USDA policy and procedures for new product license applicants	Veterinary biologics and diagnostics	USDA-APHIS		Technical guidelines used for licensing products developed through rDNA or hybridoma technology.

AUTHORITY		AFFECTED PRODUCTS	AFFECTED		

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Memorandum of Understanding between USDA and FDA for Defining Jurisdiction of Animal Drugs. (See 47 FR 26458, June 18, 1982)	Agreement between APHIS and FDA regarding responsibility for regulating animal biologic products as biologics under the VST Act or as drugs under the FD&C Act.	Veterinary biologics or drugs	HHS-FDA USDA-APHIS		
Toxic Substances Control Act (TSCA) (5 USC 2601-2929)	TSCA applies to "chemical substances" defined as "any organic or inorganic substance of a particular molecular identity including...any combination of such substances ...occurring in nature..." TSCA requires premanufacture review of new chemical substances and authorizes regulation of new and existing substances.	Industrial chemicals produced by genetically engineered organisms or by-products (e.g., enzymes); organisms used in general industrial, commercial, and consumer applications, such as water pollution control, mineral leaching, drain cleaning, etc.; organisms used to make TSCA or Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) chemicals	EPA, agencies that manufacture "chemical substances" for commercial purposes.	Drugs, biologics, foods, food additives, cosmetics, pesticides and tobacco and tobacco products are excluded from TSCA review.	Provides broad range of authority over "chemical substances."
Section 5(a)(1)(A)	Requires submission of premanufacture notice (PMN) for "new chemical substances"	New products (including organisms) used for purposes listed above	EPA		Mandatory requirement; 90-day review, extendable for "good cause" to 180 days. EPA must make a finding of potential risk or exposure to regulate. R&D in small quantities (including small quantities of biotechnology R&D) are exempt from PMN. "Small quantities" as defined by rule would exempt most field testing.
Section 5(h)(3)	Exempts research and development activities from PMN requirements	Organisms and other substances used in the lab; products sold solely for R&D use (e.g., restriction enzymes)	EPA		
Section 5(a)(1)(B)	Authorizes EPA to require by rule reporting before "chemical substances" are used for "significant new uses"	TSCA chemicals proposed for new use	EPA		Discretionary. "Significant new uses" must be defined by rule. No regulations currently in place that affect biotechnology.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Regulations: 40 CFR 720	PMN requirements	TSCA Chemicals	EPA, agencies that manufacture "new chemical substances" for commercial purposes.		Interprets mandatory statutory requirements.
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 USC 136-136y)	Requires registration of pesticides before distribution or use (pesticide broadly defined as "any substance or mixture...intended for preventing, destroying, repelling or mitigating any pest, and ...intended for use as a plant regulant, defoliant, or dessicant.")	Biological pesticides (e.g., microorganisms or their chemical products).	EPA, USDA-FSIS, HHS-FDA	EPA sets tolerance levels for pesticide residue in the food chain which FDA and USDA-FSIS enforce.	Pesticides defined to include living organisms. EPA review period could vary from one to several years. Fourteen microbial pesticides (non-engineered) have been approved.
Section 3(c)(2)(A)	Authorizes EPA to publish "guidelines" specifying kinds of information needed for registration.		EPA		
Section 5	Authorizes EPA to issue experimental use permits for limited uses before registration.		EPA		120 day review period; can be extended.
Section 25(b)	Authorizes EPA to exempt a pesticide from registration.		EPA, USDA-APHIS	USDA has responsibility for higher plants and animals that are considered pesticides (40 CFR 162.5(c)(4)).	Higher plants and animals and certain pheromone attractants have been exempted.
Regulations: 40 CFR 158	Data requirements for pesticide registration including genetically modified microbial pesticides	Microbial pesticides	EPA	Section 3 of FIFRA	Includes data requirements for microbial pesticides. Testing requirements are tiered, with more complicated tests required where certain criteria are met. Additional requirements for genetically modified and other microbial pesticides determined on a case-by-case basis.

4

| AUTHORITY OR | DESCRIPTION | AFFECTED PRODUCTS OR | AFFECTED AGENCIES | CROSS-REFERENCES | NOTES |

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
40 CFR 162	Pesticide registration regulations	Microbial pesticides	EPA, USDA-APHIS DOI	Section 3 of FIFRA; Biological control agents regulated by USDA, DOI, or other Federal agencies under express statutory authority not included.	Applies to viruses, bacteria, protozoa, fungi, etc., used as pesticides. Does not apply to higher plants and animals.
40 CFR 172	Experimental use permit regulations	Field-tested microbial pesticides	EPA	Section 5 of FIFRA	120 day review period which can be extended; for land uses, generally only need permit if test covers more than 10 acres, but EPA has authority to require permits for less than 10 acres under certain circumstances.
"Microbial Pesticides; Interim Policy on Small Scale Field Testing" (49 FR 40659 (1984))	EPA policy requiring notification prior to small scale field tests with certain microbial pesticides	Microbial pesticides containing nonindigenous or genetically altered microorganisms	EPA	Section 5 of FIFRA and 40 CFR 172	Applies to tests conducted on 10 or less acres of land or 1 or less acre of water (i.e., small scale field testing)
Guidelines: Pesticide (Subdivision M) Assessment Guidelines (October (1982))	Provides guidelines for developing data required under 40 CFR 158.	Microbial pesticides	EPA		
Reorganization Plan No. 3 of 1970, Section 2(4)(5 USCA App.)	Authorizes EPA to establish tolerances for pesticide residues in food chain	Pesticide products used so as to result in residues in food chain	EPA, HHS-FDA, USDA-FSIS	FD&C Act Sections 406, 408, 409 EPA sets pesticide standards which are enforced by FDA and USDA.	
Regulations: 40 CFR 162.7(d)(3)(v) and 162.18-4(a)(4)	Requires tolerances before registration	Pesticides to be registered for food or animal feed use	EPA, HHS-FDA, USDA-FSIS		
Guidelines:					
"Guidelines for Research Involving Recombinant DNA Molecules" (49 FR 46266 (1984))	Specifies practices for constructing and handling rDNA molecules and organisms and viruses containing rDNA molecules. Compliance is required for institutions that receive support for rDNA research from NIH.	All rDNA research conducted by institutions receiving NIH support as well as NIH itself.	All involved in rDNA research, primarily HHS and USDA. Administered by HHS-NIH with the advice of the rDNA Advisory Committee (RAC)	Biotechnology R&D exempt from PMN requirement of TSCA.	Voluntary compliance for institutions that receive no NIH rDNA research funding.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
"Points to consider in the design and submission of human somatic-cell gene therapy protocols."	NIH technical guidance for preparing proposals involving human gene therapy for consideration under Section III-A-4 of the NIH Guidelines for Research Involving Recombinant DNA Molecules.	All human somatic cell gene therapy research conducted by institutions receiving NIH support as well as NIH itself.	HHS-NIH		
II. POST MARKETING REQUIREMENTS					
A. Occupational Safety					
"Biosafety in Microbiological and Biomedical Laboratories"	CDC/NIH manual which describes combinations of standard and special microbiological practices, safety equipment, and facilities that constitute biosafety levels 1-4 and serve as recommendations for working with a variety of infectious agents in the lab.	All clinical, public health, and private diagnostic labs and research labs using pathogenic microorganisms.	All involved in diagnostic public health and research HHS, USDA, EPA		Voluntary compliance for all Federal, State, and private labs.
Occupational Safety and Health Act (29 USC 651 et seq.)	Regulation of the workplace to assure that no employee will suffer diminished health as a result of conditions in the workplace; authority to publish standards with which employers must comply; authority to fund research and development; authority to "describe exposure levels" (risk assessment). No license or premarket approval required.	Exposure to inorganic and organic chemicals and microbials.	DOL-OSHA, HHS-CDC-NIOSH	In setting standards, the Secretary of Labor may use information provided by "an interested person" including the NIEHS and NCI of NIH, the NBS of Commerce, NIOSH of CDC, the NTP of HHS. NIOSH recommends standards to OSHA. OSHA has the ability to regulate any workplace so that, no matter who approves a given technology or environmental release, OSHA can intervene to protect employees. Note: The Mine Safety and Health Act will apply in similar fashion in those cases where biotech is used to extract minerals.	The statute uses several adjectives that are subject to interpretation such as serious physical harm and material impairment of health. The Secretary of Labor may grant a waiver to standards under certain specific and narrowly defined conditions. Standards may be effective immediately in cases of imminent hazard. Important: States have the right to enforce their own standards where no Federal standards exist and they have the right to administer Federal standards under plans approved by the Secretary of Labor.

AUTHORITY OR	DESCRIPTION	AFFECTED PRODUCTS OR	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES

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Regulations:					
29 CFR 1900-1910 Workplace Standards	Sets regulatory standards for specific workplace hazards	Primarily toxic chemicals	DOL-OSHA HHS-CDC-NIOSH	NIOSH recommends standards to OSHA	There is no general industry standard requiring compliance in the biotech area. Specific standards will be developed in the event that existing standards prove inadequate.
30 CFR 11 Workplace Respirator Standards	Sets a regulatory standard for respirators	Respirable toxic substances	HHS-CDC-NIOSH DOL-Mine Safety and Health Admin. (MSHA)	OSHA and MSHA require adherence to respirator standards	NIOSH has a regulatory role here.
29 CFR 1910.20 Access to Employee Exposure and Medical Records	Provides access to plant information on toxic substances and harmful physical agents and to medical monitoring data related to exposures	Toxic substances and physical and biological agents	DOL-OSHA HHS-CDC-NIOSH		
29 CFR 1910.1200 Hazard Communication	Requires manufacturers and importers to evaluate hazards of their products and communicate this information to employees through labels, material safety data sheets and training	Toxic substances	DOL-OSHA		Could include biological agents
TSCA Section 6	Authorizes EPA to regulate the manufacture, processing, distribution in commerce, use, and disposal of "chemical substances"	TSCA "chemical substances"	EPA, CPSC, OSHA, DOT		Discretionary authority can be exercised if EPA finds a substance "will present" an unreasonable risk. Can be used to impose controls through all phases of manufacture, processing, use and disposal. Unlike PMN authority (Sec. 5(a)(1)(A)), Section 6 can be applied to R&D substances. No regulation affecting biotechnology in effect.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
B. Drug Manufacturing Practices					
FD&C Act Section 501(a)-(e) (21 USC 351) Regulations: 21 CFR 210, 211, 225, 226	FDA establishes "current good manufacturing practices" (CGMPs) for drug products through regulation that are mandatory for manufacturers	Drugs, human biologics, and medicated feeds	HHS-FDA		Certain aspects are also applicable to premarketing manufacture.
C. Hazardous Waste					
Comprehensive Environmental Response, Compensation, and Liability Act (Superfund Act) (42 USC 9601-9657)					
Sections 102, 103	Requires reporting of releases of "reportable quantities" of hazardous substances	Substances identified as hazardous under Sections 101 or 102	EPA-Nat'l Response Center		"Hazardous substance" refers to (1) certain substances regulated under the Clean Water Act, Clean Air Act, TSCA, and Resource Conservation and Recovery Act, and (2) any other substances that may present substantial danger to public health, welfare, or the environment and are listed by EPA under Section 102 of Superfund Act. Some genetically engineered organisms or byproducts could meet the latter test; none now listed.
Section 104	Provides health assessment and specific public health activities at superfund sites	Substances identified as hazardous under Sections 101 or 102	HHS-Agency for Toxic Substances & Disease Registry (ATSDR)		
Section 105	Requires EPA to develop National Contingency Plan (NCP) for cleanup of hazardous substances; must specify methods for cleanup (e.g., use of biological materials).	Products used to degrade hazardous substances.	EPA, other emergency response agencies (e.g., HHS-CDC, FEMA, DOT)		
Regulation: 40 CFR 300	National Contingency Plan	Products used to degrade hazardous substances	EPA, other emergency agencies		Regulation identifies criteria for responding to releases and lists use of microorganisms for waste treatment.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Resource Conservation and Recovery Act (RCRA) (42 USC 6901-6987)					
Section 3001	Authorizes EPA to list and identify hazardous waste with assistance from ATSDR and the National Toxicology Program (NTP)	Waste identified as hazardous.	EPA, HHS-ATSDR, NTP		Discretionary authority to list waste as hazardous; no living organisms now listed. However, a biotechnology waste could be listed if concern warrants. If mixed with listed hazardous waste or if they exhibit hazardous waste characteristics, biological wastes could be regulated as hazardous waste.
Sections 3002-3004	Standards applicable to generators, transporters, and owners and operators of facilities that treat, store, and dispose of hazardous waste.	Solid waste identified as hazardous waste under RCRA.	EPA, DOT	DOT's authority under Hazardous Materials Transportation Act overlaps EPA's RCRA authority, but DOT and EPA have memorandum of agreement to divide responsibilities. (45 FR 51645 (1980))	
Section 3005	Requires permits for treatment, storage, disposal of hazardous waste.	Waste identified as hazardous.	EPA, DOT		
Sections 4005(a) and 1008	Prohibits "open dumping" of solid wastes	Solid waste	EPA		Biological products or byproducts would be subject to the prohibition when disposed.
Regulations:					
40 CFR 260	Hazardous waste management system — general requirements		EPA		
40 CFR 261	Identification and listing of hazardous waste		EPA		
40 CFR 260-267	Standards for generators, transporters, and owners or operators of facilities that treat, store, and dispose of hazardous waste.		EPA, DOT	DOT regulates transportation of hazardous "materials."	Would affect industries using biotechnology only to the extent they generated wastes identified as hazardous. No living organisms listed.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
40 CFR 270 Marine Protection, Research, and Sanctuaries Act (Ocean Dumping) (33 USC 1401-1445)	Hazardous waste permit program		EPA		
Section 102, 103	Prohibits ocean dumping without a permit, authorizes EPA to issue permits for dumping all materials except dredged materials and materials specifically prohibited by statute.	Microbial products used in pollution control; waste and byproducts from manufacture, use, etc.	EPA, Corps of Engineers	Corps of Engineers authorized to issue permits for dredged material.	
Regulations: 40 CFR 227-228	Criteria for approving permits; prohibits dumping of wastes containing living organisms that would endanger health or the environment; exempts dredged material from that prohibition.		EPA, Corps of Engineers		
D. Other Containment and Transportation Requirements					
Federal Meat Inspection Act (21 USC 601 et seq.) Regulations: 9 CFR 301 et seq.	Regulates, through mandatory inspection, the slaughtering, preparation, labeling, marking, distribution of meat and meat food products to prevent "adulterated" or "misbranded" meat and meat food products from entering commerce.	Meat and meat food products (specifically cattle, sheep, swine, goat, horse, mule, or other equine). See definition in 9 CFR 301.2 (tt) and (vv)	USDA-FSIS	FDA sets residue tolerance levels for animal drugs in food-chain animals. FDA's regulatory authority is found in 21 CFR 556.	Both the Federal Meat Inspection Act and the Poultry and Poultry Products Inspection Act determine whether regulated articles contain any "biological residues" (see definitions in 9 CFR 301.2 (22) and 381.1 (7), and contain specific recordkeeping, buying, selling, and transportation requirements affecting foreign, interstate, and intrastate commerce.
Poultry and Poultry Products Inspection Act (21 USC 451 et seq.) Regulations: 9 CFR 381	Regulates, through mandatory inspection, the slaughtering, preparation, distribution, disposition, marking, and labeling of poultry and poultry products to prevent "adulterated" or "misbranded" poultry and poultry products from entering commerce.	Poultry (specifically, any domesticated bird--chicken, turkey, ducks, geese, or guineas, whether live or dead) and poultry products. See definition in 9 CFR 381.1 (40) and (41).	USDA-FSIS		

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Hazardous Materials Transportation Act (49 USC 1801 et seq.) Regulations: 49 CFR 107, 171-177	Regulation of transportation of hazardous materials. Shippers must register with DOT. Authorizes halt of shipping immediately for "imminent hazard."	Etiologic agents	DOT-Ofc of Hazardous Materials Regulation	DOT consults with the ICC which is responsible for enforcement where it has authority. DOT has an agreement with EPA (RCRA) on duplicative authorities.	May regulate packing, labeling, and routing as well as the manufacture of packaging. Secretary may exempt shippers if they achieve a level of safety higher than the level of safety required or if no standard exists and public safety is maintained.
PHS Act Section 361 (42 USC 264) Regulations: 42 CFR 71-72	Authorizes regulation of introduction and control of communicable diseases, interstate transportation of etiologic agents and importation of etiologic agents and vectors.	Etiologic agents	HHS-CDC, FDA, NIH		The requirements of this regulation are in addition to and not in lieu of any other requirements of DOT, USDA, or EPA for importation or interstate transport.
Section 102, Organic Act of 1944, as amended, and the Act of April 6, 1937, as amended (7 USC 147a, 148, 148a-e) Regulations: 7 CFR 300-399	General authority to "carry out operations or measures to detect, erradicate, suppress, control, or to prevent or retard the spread of plant pests." Provides for inspection of plants and plant products offered for export.	"Plant pests" are defined as: "any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants."	USDA-APHIS	EPA also has authority over organisms that could act as plant pests.	Authority extends to cooperative action with States or political subdivisions, farmers associations and similar associations, individuals and governments of Western Hemisphere Countries.

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Federal Plant Pest Act, as amended (7 USC 150aa-jj) and Plant Quarantine Act, as amended (7 USC 151-164a, 166-167) Regulations: 7 CFR 300-399	General authority to regulate the importation into and the dissemination within the U.S. of plant pests, nursery stock, and other plants and plant products, and any product or article which may contain a plant pest at time of movement. Authority for USDA to import for scientific or experimental purposes any class of nursery stock, plants, fruits, vegetables, roots, bulbs, seeds, or other plant products for which importation may otherwise be forbidden.	"Plant pests" are defined to be consistent with the definition of "plant pests" in Sec. 102 of the Organic Act.	USDA-APHIS		Authority to bring civil and criminal actions for violations of the Act or regulations promulgated thereunder. USDA may stop, and without a warrant, inspect, search, seize, examine, destroy or otherwise dispose of specified articles found to be moving or to have been moved in interstate commerce or to have been brought into the U.S. in violation of the Act or of a quarantine or order. In extraordinary emergency situations, USDA may stop intrastate activity as well.
"Animal Quarantine Laws" (21 USC 102-105; 21 USC 111; 21 USC 114a-114h; 21 USC 115-130; 21 USC 134-134h 21 USC 135-135b) Regulations: 9 CFR 1-199	In general, the animal quarantine laws regulate the importation, exportation, and interstate movement of certain animals to prevent the introduction or spread of communicable diseases of animals or of the contagion of any contagious, infectious, or communicable disease of animals or/and live poultry.	21 USC 101-105 regulates cattle, sheep and other ruminants and all swine imported into or intended for export from the U.S. 21 USC 111 regulates that which could introduce or cause the dissemination in the U.S. of the contagion of any contagious, infectious, or communicable disease of animals and/or live poultry.	USDA-APHIS		

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AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Federal Noxious Weed Act of 1974 (7 USC 2801-2813) Regulations: 7 CFR 360	Authority to issue permits to regulate the movement of noxious weeds into or through the U.S. Authority to regulate the sale, purchase, barter, exchange, advertisement, giving, or receiving of any noxious weed.	"Noxious weed" is defined as "any living stage (including but not limited to seeds and reproductive parts) of any parasitic or other plant of a kind or subdivision of a kind, which is of foreign origin, is new to or not widely prevalent in the U.S., and can directly or indirectly injure crops, other useful plants, livestock, or poultry or other interests of agriculture including irrigation or navigation or the fish and wildlife resources of the United States or the public health."	USDA-APHIS	No action may be taken to regulate interstate movement unless a State also takes a cooperative action to erradicate the noxious weed in its State.	Authority to seize, quarantine, treat, destroy or otherwise dispose of any product or article of any character whatsoever, or means of conveyance, which is moving into or through the U.S. or interstate and which is believed to be infested by any noxious weed, or contains any noxious weed, or which was infested or contained any noxious weed at the time of movement.
TSCA Section 13	Substance imported into the US must be in compliance with TSCA.	TSCA "chemical substances"	EPA, USDA-APHIS Treasury Dept.		Mandatory requirement.
Regulations: 40 CFR 707 19 CFR 12, 127	Section 13 import provisions; requires companies importing "chemical substances" to certify compliance with TSCA		EPA, USDA-APHIS Treasury Dept.	Federal Plant Pest Act, Federal Noxious Weed Act, "Exotic Organisms" Executive Order 11987 also regulate imports	Rules were issued by Treasury Department and EPA.

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III. EXPORT CONTROLS	Technical Data				
Export Administration Act (540 USC 2401, et seq.) Regulations: 15 CFR 368-399	All non-public technical data exported to Eastern Bloc Countries, Libya, Cuba, N. Korea, Afghanistan, Kampuchea, and Vietnam requires a validated license.	Technical data related to all technologies.	Dept. of Commerce-Int'l Trade Admin. (DOC-ITA)		Statute provides discretionary authority to restrict technical data for three reasons: a) Foreign Policy b) National Security c) Short Supply Although authority to administer the EAA terminated, it was extended indefinitely by Executive Order 12370 of March 30, 1984.
	Commodities				
	Listed products cannot be exported to any country except Canada without a validated license from the Department of Commerce.	Bacteria, fungi, protozoa, virus, human and animal vaccines, human and animal peptides and proteins, rDNA, nucleotides and side antibiotics and diagnostics, amino acids, vitamins, enzymes, pesticides, herbicides and seeds	DOC-ITA		Restrictions generally apply to Soviet Bloc countries and those countries with which we do not have diplomatic relations.
IV. RESEARCH AND INFORMATION GATHERING					
A. Research					
PHS Act Section 301 (42 USC 241)	Biomedical research authority, both intramural and extramural research	Basic and applied research related to foods, drugs, biologics, new surgical techniques, chemicals as carcinogens (NIEHS, NTP, NCTR), medical devices.	HHS-NIH, ADAMHA, CDC, FDA		HHS has many other research authorities for specific diseases, but Section 301 is sufficient to do biomedical research related to human health.
Organic Act of 1862 (7 USC 2201-2204)	Agricultural research authority, both intramural and extramural	Plants and animals	USDA		USDA also has many authorities for research, just as NIH, including: Domestic Animals, Dairy Industry, Aboretum, Forest and Rangeland, Cotton and Nutrition

AUTHORITY OR	DESCRIPTION	AFFECTED PRODUCTS OR	AFFECTED	CROSS-REFERENCES	NOTES

AUTHORITY OR GUIDELINE	DESCRIPTION	AFFECTED PRODUCTS OR PROCESSES	AFFECTED AGENCIES	CROSS-REFERENCES	NOTES
Organic Act of 1944 Section 101(d) (7 USC 430)	Authority to purchase and test samples of all tuberculin, serums, antitoxins, or analogous products, of foreign or domestic manufacture, which are sold in the U.S. for the detection, prevention, treatment or cure of diseases of domestic animals.		USDA-ARS		
TSCA, FIFRA, RCRA, Clean Water Act	Environmental research authority, both intramural and extramural	TSCA "chemical substances," pesticides, hazardous wastes, air and water pollutants	EPA		
B. Information Gathering					
Federal Seed Act (7 USC 1551-1611) Regulations: 7 CFR 201 et seq.	Requires specific recordkeeping on labeling, importation and interstate movement of seeds.	Agricultural and vegetable seeds	USDA-APHIS		The term "treated" means given an application of a substances or subjected to a process designed to reduce, control, or repel disease organisms, insects, or other pests which attack seeds or seedlings growing therefrom.
TSCA Section 4	Authorizes EPA to require manufacturers by rule to test specific "chemical substances"	TSCA "chemical substances"	EPA		Discretionary authority; could be be used to require testing of specific products developed through genetic engineering (both organisms and chemicals produced by organisms); could be used to support activities of other agencies (e.g., OSHA, CPSC). No regulations affecting biotechnology now in effect.
TSCA Section 8(a)	Authorizes EPA to require manufacturers and processors to submit information on a product's identity, exposure, available health and safety data, etc.		EPA		Discretionary authority invoked by rule; can be used to support other agencies; small businesses generally exempt from reporting. No biotechnology rule now in effect.
TSCA Section 8(d)	Authorizes EPA to require submission of health and safety studies on products subject to TSCA.		EPA		Discretionary authority invoked by rule; no biotechnlogy rules now in effect.

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TSCA Section 8(e)	Requires submission of information on substantial risks from "chemical substances."	TSCA chemicals	EPA		Mandatory requirement if substance subject to TSCA and information shows substantial risk.
Guideline: 43 FR 11110 (1978)	Policy for submitting information under Sec. 8(e)	TSCA chemicals	EPA		Mandatory requirement if substance subject to TSCA.
FIFRA Section 6(a)(2)	Continuing obligation for registrants to supply data	All registered products	EPA		After registration, registrants must report additional information on unreasonable adverse effects of pesticide. The "interpretation" is undergoing revision currently.
Guideline: Interpretation of Requirements on Registrants by Section 6(a)(2), August 23, 1978 (43 FR 37611 and 44 FR 40716)					
FIFRA Section 3(c)(2)(B)	Authorizes EPA to request additional data in support of registration	All registered products	EPA		After registration, EPA may require additional data from registrants in order to maintain registrations.
V. PATENTS					
Patent and Trademark Laws (35 USC 1 et seq.)	Patent process	All products and devices	DOC-Patent and Trademark Office	Patent for new drugs issued well before FDA premarket approval. Important: Government research institutions can offer Institutional Patent Agreements with universities for 5 to 8 years after market appproval under PL 96-517.	
Regulations: 37 CFR					
Plant Variety Protection Act (7 USC 2321 et seq.)	Granting of patents for sexually reproduced varieties of plants.	New varieties of sexually reproduced plants	USDA-Agriculture Marketing Service (AMS)		
Regulations: 7 CFR 180					
Judicial Decisions:					
Diamond v. Chakrabarty 447 US 303 (1980)	Supreme Court held that genetically engineered bacterium was patentable.			Court cited NIH guidelines in decision as addressing the problems of genetic engineering.	

AUTHORITY

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VI. AIR AND WATER EMISSIONS					
Clean Air Act (42 USC 7401-7642)	Requires emission standards to be set for hazardous air pollutants where there is no applicable ambient air quality standard.		EPA		Discretionary authority; no genetically engineered organisms now included, but could be set for biotechnology products if concern warranted.
Regulations: 40 CFR 61	Sets national emission standards for specific hazardous air pollutants		EPA		
Clean Water Act (33 USC 1251-1376)	Pollutant discharges without National Pollutant Discharge Elimination System (NPDES) permit unlawful. Pollutant defined to include living organisms; requires EPA to establish effluent limitations for point sources.	Organisms or byproducts that are discharged into the waters of the U.S.	EPA, States	States establish water quality standards. States or EPA issue permits which incorporate technology-based limits and water quality-based limits.	Regulations developed for drug manufacturers, pesticide manufacturers and hospital. (See 40 CFR 401-469, below.)
Regulations:					
40 CFR 122, 125	NPDES permit program		EPA, States		Implemented by States and EPA. Source employing biotechnology will be required to adhere to permit restrictions.
40 CFR 120, 121	State water quality standards, State certification requirements		EPA, States		
40 CFR 401-469	Effluent guidelines and standards for categories of point sources		EPA, States		Specific biotechnology category not issued, but some categories could involve biotechnology products (e.g., part 439, pharmaceutical manufacturing; part 460, hospitals; and part 455, pesticides).
Safe Drinking Water Act (SDWA) (42 USC 300f et seq.)					
Section 300g-1	Authorizes promulgation of maximum containment levels for drinking water from public water systems.	Any physical, chemical, biological or radiological substances or matter in drinking water	EPA		No genetically engineered biological substances now included. Could be regulated if it presents a known or anticipated adverse effect on health.

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Section 300h-1	Requires state programs to regulate any injection of any substance into a well; provides for minimum regulatory standards for such programs in order to prevent underground injection that endangers drinking water.	Any substance injected into the subsurface through a well	EPA		See 40 CFR Parts 144, 145, and 146. If disposed of by deep well injection, subject to stringent requirements for Class I wells regarding well construction, operation, monitoring, and reporting; if not a deep well, then would be Class V, subject only to a general prohibition on endangerment to drinking water sources.
VII. REQUIREMENTS FOR FEDERAL AGENCIES					
National Environmental Policy Act (NEPA) Section 102(2)(C) (42 USC 4321-4361) Regulations: 40 CFR 1500-1508	Requires all agencies to prepare environmental impact statements on "major Federal actions significantly affecting the environment."		All Federal Agencies	Administered by Council on Environmental Quality	Applies only to Federal actions (e.g., federally funded projects or premarket approval). Each agency develops its own guidelines or regulations under this Act. Procedural requirements generally held inapplicable to EPA actions.
Endangered Species Act of 1973, as amended, Section F (16 USC 1536) Regulations: 50 CFR 402	Requires Federal agencies to insure that their activities or programs will not jeopardize the continued existence of a listed species.	All species of fish, wildlife and plants listed pursuant to the Endangered Species Act.	All Fed. agencies	Consultation required with the U.S. Dept. of the Interior or the National Marine Fisheries Service.	
Executive Order 11987 "Exotic Species"	Orders Executive Agencies (to extent permitted by law) to restrict the importation into the U.S., and introduction of exotic specimens into the natural ecosystems. Exempts from provisions of Executive Order 11987 the introduction or exportation of exotic species when USDA or USDI finds that the introduction or exportation will not have an "adverse effect on natural ecosystems."	"Exotic Species" is defined to mean all species of plants and animals not naturally occurring, either presently or historically, in any ecosystem of the U.S.	All Fed. agencies		Secretary of the Interior in consultation with Secretary of Agriculture is required to develop and implement by rule or regulation a system to standardize and simplify the requirements, procedures, and other activities appropriate for implementing the provisions of Executive Order 11987. No rule has been developed.

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Section 309 of Clean Air Act, as amended, (42 USC 7609), PL 91-604	Requires EPA to review and comment publicly on the environmental impacts of Federal activities including actions for which environmental impact statements are prepared.		All Fed. agencies	Council on Environmental Quality regulations 40 CFR Part 1504.1(b)	

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